Use of Influenza A (H1N1) 2009 Monovalent Influenza Vaccine in Pregnant Women

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Why do the Centers for Disease Control and Prevention (CDC) and its Advisory Committee on Immunization Practices (ACIP) recommend that pregnant women receive seasonal and influenza A (H1N1) 2009 Monovalent vaccines?

- Pregnant women, compared to the general population, are at increased risk for severe disease and serious complications, including death, from influenza. Pregnant women who are otherwise healthy have been severely impacted by the pandemic 2009 H1N1 influenza virus (formerly called "novel H1N1 flu" or "swine flu"). In comparison to the general population, a greater proportion of pregnant women infected with the pandemic 2009 H1N1 influenza virus have been hospitalized and died. This is why pregnant women are among the highest priority groups for immunization.
- The CDC and its ACIP recommend that pregnant women receive both the inactivated Influenza A H1N1 (2009) monovalent vaccine and the inactivated seasonal influenza vaccine during any stage of pregnancy. These recommendations are based on the increased risks of influenza and its complications for pregnant women, the protection that the influenza vaccines can provide for both pregnant women and their newborns, and the track record of safety of the licensed inactivated seasonal influenza vaccines.

What do the product labels state regarding use of influenza A (H1N1) Monovalent vaccine in pregnant women?

- All seasonal influenza vaccines as well as the Influenza A (H1N1) 2009 monovalent vaccines are approved for adults.
- Influenza vaccines, both seasonal and the recently licensed Influenza A (H1N1) 2009 monovalent vaccines, are not contraindicated for use in pregnancy. As with many other vaccine products, the manufacturers did not conduct clinical studies specifically to evaluate the influenza vaccines in pregnant women prior to approval of these vaccines. Therefore, the pregnancy section of the prescribing information for the licensed influenza vaccines carry either a Category B or C. This allows influenza vaccines to be given to pregnant women if there is a determination that the vaccine is clearly needed, as recommended by the ACIP.

What type of seasonal influenza vaccine should pregnant women receive?

- There are two types of influenza vaccines. One is the inactivated influenza vaccine ("flu-shot") that is given with a needle, usually in the arm. This is the type of vaccine that ACIP recommends pregnant women should receive.
- The other type of influenza vaccine, "nasal - spray" influenza vaccine (sometimes called LAIV for "live attenuated influenza vaccine") is made with live weakened influenza virus. The live attenuated influenza vaccine is not recommended by the ACIP for use in pregnancy.

Does FDA support the CDC and ACIP recommendations to vaccinate pregnant women to help prevent influenza disease?

- Yes. FDA supports the recommendation of CDC and the ACIP that pregnant women receive vaccinations to help protect them against both the pandemic 2009 H1N1 influenza virus and seasonal influenza.

What is known about the safety of influenza vaccines in pregnant women?

- Studies of several thousand pregnant women in the scientific literature have shown that inactivated seasonal influenza vaccines are safe during pregnancy. They have shown no evidence for harm to pregnant women, the pregnancy or to newborns of vaccinated women. In addition, FDA and CDC's routine monitoring of adverse events has not raised safety concerns.
- The FDA-approved Influenza A (H1N1) 2009 monovalent vaccines are made in the same licensed facilities and with the same manufacturing processes used to safely produce hundreds of millions of doses of seasonal influenza vaccine every year.
- In addition, before they can be used, all Influenza A (H1N1) 2009 monovalent vaccines must undergo the same rigorous FDA manufacturing oversight, product quality testing and lot release procedures that apply to seasonal influenza vaccines.
- Because of the scientific information in the literature, the fact that FDA-licensed manufacturers are producing the Influenza A (H1N1) 2009 monovalent vaccine following the same processes as for their seasonal influenza vaccines, and FDA-oversight of manufacturing, product quality testing and lot release procedures, FDA has a high degree of assurance of the safety of both seasonal and Influenza A (H1N1) 2009 monovalent vaccines for pregnant women.

- Potential side effects of the Influenza A (H1N1) 2009 monovalent vaccines are expected to be similar to those of seasonal influenza vaccines. The most common side effect is soreness at the injection site. Other side effects may include mild fever, body aches, and fatigue for a few days after the inoculation. As with any medical product, unexpected or rare serious adverse events may occur.

- The Influenza A (H1N1) 2009 inactivated (flu-shot) vaccines that have been licensed are available in both single dose and multi-dose preparations. Multi-dose preparations are formulated with thimerosal, a mercury-containing preservative used to ensure that the vaccine does not become contaminated after the vial has been opened. Single dose preparations contain no thimerosal, or only trace amounts. Studies have shown that there is no known harm from thimerosal preservative-containing vaccines. In 1999, FDA conducted a review of thimerosal in childhood vaccines and found no evidence of harm from the use of thimerosal as a vaccine preservative, other than local hypersensitivity reactions. The Institute of Medicine's Immunization Safety Review Committee reached a similar conclusion in 2001, based on a review of available data, and again in 2004, after reviewing studies performed after its 2001 report. Since then, additional studies have been published confirming these findings. Thus, pregnant women may receive either preservative-free or thimerosal preservative-containing influenza vaccine.
- All influenza vaccines continue to be produced using eggs. For this reason, a previous history of severe, life threatening allergies to eggs are a contraindication to the use of influenza vaccine.

How will the Influenza A (H1N1) 2009 Monovalent vaccines be monitored for safety?

- FDA and CDC will closely monitor the safety of the Influenza A (H1N1) 2009 vaccines. FDA is collaborating with CDC, HHS, private partners and other government agencies to enhance adverse event safety monitoring during and after the Influenza A (H1N1) 2009 vaccination program in all populations, including pregnant women. In addition, while no safety concerns have been identified to date, a project will be initiated this fall to focus on the safety of the pandemic (H1N1) influenza vaccine and of antiviral medicines for pregnant women and their newborns.

Will the seasonal influenza vaccine provide protection against the 2009 H1N1 influenza virus?

- No. This year's seasonal influenza vaccine is not expected to provide protection against the 2009 H1N1 influenza virus. Therefore, it is recommended that pregnant women receive both the 2009 H1N1 and seasonal vaccines.